

Taboos and clinical research in West Africa

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Editor's note

To be ethical, clinical research must seek to secure the continued and informed consent of the subjects, to avoid inflicting suffering and to obtain a positive observable benefit for the subjects outweighing inherent risks. In societies with low levels of education and strong traditional, social or religious beliefs these aims may be difficult to achieve. Research ethics must be intimately related to the circumstances of the study population. For the Nigerian case, an administrative structure of ethical review committees is suggested to ensure this.

The ideal moral and ethical expectations from clinical research scientists are that they should enforce the principles of 'informed consent', avoid inflicting mental and physical suffering, guarantee that observed benefits outweigh inherent risks, protect research subjects from procedural incompetence and accept that initial consent becomes void when side effects are potentially or overtly harmful. It is, however, obvious that the translation of these ideals into pragmatic realities continues to be frustrated by the complexities of human society and environment. To inform requires an efficient system of communication and to consent implies understanding. The achievement of both is one of the highest demands of the intellect. Where these are relatively undeveloped or impaired by poverty, hunger and disease, the ideal morality or ethics in clinical research may be assumed to be at risk of collapse in the milieu of alien cultural demands and social taboos.

The socio-cultural and religious taboos that still bind large populations in West Africa are many, but a few relevant examples will suffice:

- a) In some parts of West Africa, to remove a portion of the human body pre- or post-mortem is believed to deprive the subject of that organ in the life beyond.
- b) In a different setting, it is not uncommon for the 'native doctors' to dismember corpses for the purpose of preparing potions of doubtful value for diverse reasons. The awareness of this practice in a community strongly negates consent in any study for which biopsy material is required.
- c) Since the purpose of most sacrifices is to spill

blood, a large number of West Africans associate blood letting with part of a sacrificial exercise.

d) Large populations of West African women, particularly among the Yorubas of Western Nigeria, do not voluntarily give an accurate number of their children. The tendency is to give fewer figures.

The origin of this practice is uncertain but it is generally believed to have originated as a protection of their children from the slave merchants of yesteryear.

We may rightly brand these examples as absurdities but the reality is that the typical West African is still a victim of his environment in which life is largely regulated by ancient customs and taboos.

If ethics is a system of moral principles or rules of conduct within a society and since the purpose of ethics in research is to take into consideration the needs and rights of the experimental subject, the question of who truly represents the interest of that society may not be easy to answer.

The Helsinki Declaration stipulates that 'concern for the interests of the subject must always prevail over the interests of science and society'. In a broad interpretation of that principle, it is difficult to see how the interests of the subject conflict with the interests of the society except, of course, if the society is not his own. Since the case for the needs of a society is often strong, the rights of the experimental subject and the ethics of the experiment must closely correlate within that society. Diana Crane, in discussing *Sociological Perspectives on Research in Human Populations*, observed that researchers on the illiterate 'tended to dehumanise the patients and to think of them as being incapable of making decisions'.¹

But it is not only the illiterate that can be dehumanised in clinical research and it is false to equate illiteracy with inability to take decisions. Since ethical standards are societally based, to prosecute the interest of the society at large may not really conflict with the right of the individual. This is not to argue that fundamental human rights are not desirable but rather that they cannot endure to the exclusion of society. It is an unrealistic expectation, if not patently undesirable, to think that the environment in which the research is conducted should not affect the researcher's ethical

attitudes and behaviour, subject, of course, to the dictates of conscience.

Let us examine the applicability of generally accepted ethical principles in the context of an illiterate population, riddled with poverty, ignorance, disease and sustained by values which are largely influenced by social taboos.

Informed consent

The limitations of informed consent are generally known and we have earlier indicated in this paper the near impossibility of its application among large populations of West Africa. The Helsinki Declaration, reasonable in the setting in which it was conceived, concedes that the 'permission from the responsible relative replaces that of the subject' in the event of consent not being directly available due to physical or mental incapacity. What it did not consider is to what extent the consenting relative is also capable of understanding. Henderson *et al*² in a smallpox vaccination research study in five areas of West Africa, found that obedience to tribal leaders in certain areas was the strongest factor which influenced the receptivity of the populations for the programme. The implication here is that decisions may be imposed at societal levels.

Avoidance of mental and physical suffering

The determination of mental and physical suffering can only be objective in extreme cases. The immorality of this situation is incontrovertible. The difficulty arises where the mental and physical suffering is not so obvious. Where the scourge of the society which the research is intended to alleviate imposes a greater mental and physical suffering, the demands of ethical principles in this situation must be given generous interpretations. We are encouraged in this concept by the observations of Hammon *et al*³ that warnings of the risks of gamma globulin injections in the prophylaxis of clinical poliomyelitis during an epidemic did not deter thousands of Americans who still volunteered for the study.

Observable benefits versus inherent risks

It is incontrovertible that observable benefits must outweigh the risks of a projected study. But is it justified to conduct an experimental study in one population for the overwhelming benefit of another population, such as in the field trial of a skin cream on African albinos for the purpose of evaluating its effectiveness against actinic dermatoses and skin cancer. Needless to say the preponderant beneficiaries of this study are not likely to be Africans. But must research objectives be *quid pro quo*?

Reversibility of initial consent

It has been implied earlier in this contribution that informed consent is unattainable among large populations of West Africa. Henderson *et al* have correctly reported that obedience to tribal leaders was a strong factor in the receptivity of some West African populations to research programmes. Our personal experience is that provision of drugs, money and food are the essential pre-requisites for patient retrieval in clinical research. Not a few of our research patients or volunteers become so dependent on these apparent kindnesses that withdrawal from the study programme becomes unthinkable—yet, we are often aware of the patient's disenchantment with the study. It is therefore hypocritical to pretend the highest ethics merely by informing a peer review committee that participants in a study were clearly informed that they could withdraw from the study. The situation is worse in an in-patient setting where even the educated cannot sometimes distinguish between what is therapeutic from what is investigatory.

Faced with these situations, it is important to relate intimately research ethics with the peculiarities of the study populations. Using Nigeria as an example, a 3-tier system for the protection of the rights of the individual is proposed (Fig.).

a) There should be a National Ethical Committee to determine the relevance of experimental proposals on large populations (such as mass immunisation programmes). It would also lay down national priorities and examine the feasibility of the research proposals while ensuring that the source and funding of such programmes do not conflict

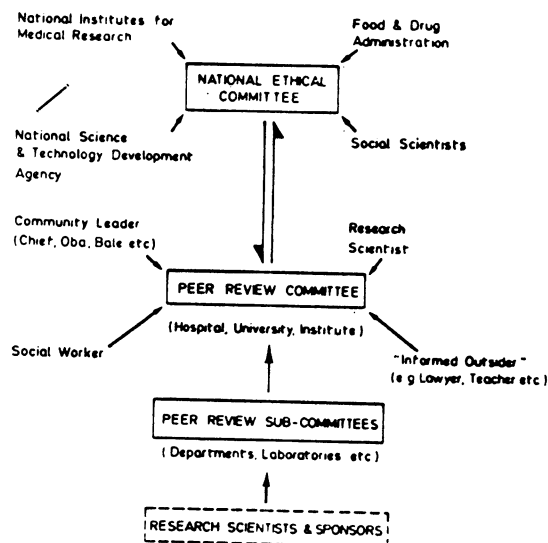


Figure A proposal for a 3-tier control of human experimentation in Nigeria.

with national policies or political goals. The inputs into this National Ethical Committee should derive from the National Institutes for Medical Research, the National Science and Technology Development Agencies, the Food and Drug Administration and sociologists.

b) There should be Peer Review Committees which may be hospital, community, university or institute based, to ensure that the highest principles of ethics in relation to the circumstances of the local community are maintained. These committees should be made up of the community leader (or Chief, Bale or Oba etc.), the research scientist, a social worker and the so-called 'informed outsider' such as a lawyer, nurse or teacher etc. who is interested in the subject. This tier of committees would maintain a close relationship with the National Ethical Committee from which it can receive or refer study programmes.

c) However, proposals to these peer review committees should normally derive from sub-committees based in the individual research departments or laboratories. They would ensure that research protocols from research workers or other sponsors are scientifically sound, well-planned and safe for human experimentation. It is at this level that research competence can best be determined.

Moore⁴ suspected unethical experiments when the research subjects were poor or when they were primitive populations, backward or uneducated people. Such suspicions can be proved unfounded where international norms are made relevant to the local circumstances and where sufficient regard is paid to the conceptions and misconceptions of the population however grotesque or mysterious.

Summary

Moral principles or the rules of conduct are based in the society. If the purpose of ethics in research is to take into consideration the needs and the rights of the experimental subject, his social milieu must then largely determine the ethical considerations of a projected study. The inability to comprehend such rights may often be due to ignorance, disease and his societal values. Blood letting, biopsy and post-mortem examinations may so conflict with local beliefs that so called 'consent' to these is much more than a surrender of the rights of the individual. It is difficult to conform with the highest principles of ethics in research in any uniform society. It is more so when the many variables are further complicated by cultural demands and social taboos. The best custodians of ethical standards must relate intimately with the norms of the local population.

References

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